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Date: May 22, 2009

By /Marvette Ferguson/
Marvette Ferguson

Docket No.: 107101-10-WCG
Confirmation No.: 8885

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Johannes BARTHOLOMAUS, et al
Serial No. : 10/718,112
Filed : November 20, 2003
For : ABUSE-PROOFED DOSAGE FORM
Art Unit : 1618
Examiner : Melissa J. Perreira

May 22, 2009

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

SIR:

In accordance with 37 CFR § 1.56 and § 1.97(b), Applicants wish to call the attention of the Examiner to the enclosed copy of "Observations by Third Parties Pursuant to Art. 115 EPC" that was submitted by a third party in opposition proceedings to Applicants' related European Patents EP 1 658 054 and EP 1 658 055 on February 2, 2009.

This document is relevant because by this document the inventor of U.S. Patent 6,488,963 B1 (hereinafter "McGinity") purports to duplicate Example 4 of US 6,488,963 B1 and show that it "inherently" produces a breaking strength of at least 500 N.

The experimental results reported in the test report of Prof. James W. McGinity, attached to the "Observations by Third Parties Pursuant to Art. 115 EPC" did not faithfully reproduce the Examples of US 6,488,963, and therefore do not establish that the products produced by said examples have the inherent breaking strength of at least 500 N, as contended by the third party.

According to the experimental report a twin-screw feeder as well as a twin-screw extruder were used, whereas according to US 6,488,963 a single-screw extruder was used (cf. US 6,488,963, col. 8, lines 29-34; col. 13, line 2). Those skilled in the art understand that the working principle of a single-screw extruder is completely different than the working principle of a twin-screw extruder. The experimental report therefore does not reproduce the examples of US 6,488,963 in this regard.

Further, according to the experimental report a 6.25 mm circular die was used, whereas according to US 6,488,963 a die with a diameter of 1 cm was used.

Still further, according to the experimental report identical temperatures of 120°C, 130°C and 155°C, respectively, were set at all zones of the extruder, whereas according to US 6,488,963 different temperatures of from 70 to 115°C were set at the

two zones of the extruder.

Furthermore, according to the experimental report screw speeds of 28 and 40 rpm were adjusted, whereas according to US 6,488,963 the screw speed was set to 25 rpm.

In addition, in the experimental report, the torque is mentioned in %, whereas according to US 6,488,963 the torque was 34, 23 and 10 Nm, respectively.

Therefore the "Observations by Third Parties Pursuant to Art. 115 EPC" and the experimental report attached to it do not in any way support any contention that McGinity US 6,488,963 teaches or suggests a dosage form having a breaking strength of at least 500 N.

Applicants are also calling the Examiner's attention to US 6,306,438 and WO 96/14058, both of which have recently come to Applicants' attention.

The commissioner is authorized to charge the fee required for this IDS to the account of the undersigned, Account No. 14-1263.

Consideration of the foregoing in relation to this application is respectfully requested.

The opponent has withdrawn its oppositions against European Patents EP 1 658 054 and EP 1 658 055 meanwhile.

CONDITIONAL PETITION FOR EXTENSION OF TIME

If any extension of time for this response is required, Applicants request that this be considered a petition therefor. Please charge the required petition fee to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fee or credit any excess to Deposit Account No. 14-1263.

Respectfully submitted,

NORRIS, McLAUGHLIN & MARCUS, P.A.

By /William C. Gerstenzang/
William C. Gerstenzang
Reg. No. 27,552

WCG/mf

875 Third Avenue, 18th Floor
New York, New York 10022
(212) 808-0700

Encs. Observations by Third Parties Pursuant to Art 115 EPC
Letter of James W. McGinity, with attached experimental report, dated January 26, 2009.